

## **II. REMARKS**

Claims 1 to 29 are pending in the subject application. Claims 1 to 21, 23 to 26 and 28 are withdrawn from examination as a result of a requirement for restriction. Claims 22, 27 and 29 were examined and stand rejected.

Claim 22 has been amended and claims 27 and 29 have been canceled without prejudice or disclaimer. New claims 30 to 41 have been added. After entry of the amendments and new claims, claims 22 and 30 to 41 are under examination.

The Office stated that in view of the Appeal Brief filed on October 18, 2004, the Office re-opened prosecution on the merits. An Office Action was issued on January 13, 2005.

Claim 22 has been amended and new claims 30 to 41 have been added in a sincere effort to remove the grounds for rejection and place the claims in condition for allowance. Support for the amendments to claim 22 is found on page 47 of the specification. New claims 30 to 41 are supported in the specification on pages 42 through 47 and 56 through 58. An issue of new matter is not raised by the amendment to claim 22 and the addition of new claims 30 through 41. Entry is respectfully requested.

In view of these amendments, reconsideration and removal of the grounds for rejection as set forth in the Office Action is respectfully requested.

### **Claim Objection**

Claim 22 stands objected to on the ground that it is in improper form. In accordance with the Office's suggestion, the claim has been amended to insert the article "A". In view of this amendment, withdrawal of this objection is respectfully requested.

**35 U.S.C. § 112, Second Paragraph**

Claims 27 and 29 stand rejected under 35 U.S.C. § 112, second paragraph, on the ground that the claims are allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office pointed out that the term “cell-matrix adhesion” recited in claim 27 has no antecedent basis in base claim 22. With respect to claim 22, the Office noted that it recites only “cell-cell adhesion”. The Office also objected to the term “suitable cell” recited in claim 27 on the ground it does not have an antecedent basis in claim 22. The Office noted that claim 22 recites “suitable tissue”.

Without conceding the correctness of the Office’s position and to place the application in condition for allowance, these claims have been canceled without prejudice or disclaimer. The rejection should therefore be withdrawn.

**35 U.S.C. § 112, First Paragraph**

Claims 22, 27 and 29 stand rejected under 35 U.S.C. § 112, first paragraph on the ground that the claims are not reasonably supported by the specification. For example, the Office stated that the specification does not enable “modulating” cell adhesion in “any tissue” with “any agent”. It is the Office’s opinion that the specification discloses an assay to disrupt cell-cell adhesion in MDCK cell monolayers and aggregation with GST-Ig<sup>a</sup>, GST-Ig<sup>b</sup> and GST-Ig<sup>c</sup>, resulting in profound disruption of intercellular adhesion. The Office stated that because there were no animals used as a model system to inhibit PKD-1 mediated adhesion of epithelial cells, it allegedly is unclear that the reliance on the *in vitro* data of MDCK cell-cell adhesion accurately reflects the relative subject efficacy of the claimed therapeutic strategy.

In response to the Office’s rejections and without conceding the correctness of the Office’s position, claim 22 has been amended and claims 27 and 29 have been canceled without prejudice or disclaimer. New claims 30 to 41 also have been added in an effort to more specifically address the Office’s stated ground for rejection.

In view of the preceding amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

### III. CONCLUSION

Applicants believe that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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